LEGISLATIVE GENERAL COUNSEL
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₵ 01-22-24 10:15 AM ₵

H.B. 132
2nd Sub. (Gray)

Representative Raymond P. Ward proposes the following substitute bill:

PHARMACY AMENDMENTS

2024 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Raymond P. Ward

Senate Sponsor: _____

LONG TITLE

General Description:

This bill allows pharmacists and pharmacy interns to substitute prescribed drugs under certain circumstances.

Highlighted Provisions:

This bill:

- defines terms;
- allows pharmacists and pharmacy interns to substitute prescribed drugs under certain circumstances;
- requires the Division of Professional Licensing, in consultation with certain licensing boards, to develop a therapeutically equivalent drug list and a therapeutically similar drug list; and
- provides rulemaking authority.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

2nd Sub. H.B. 132

58-17b-605, as last amended by Laws of Utah 2020, Chapter 372

REPEALS:

58-17b-605.5, as last amended by Laws of Utah 2015, Chapter 266

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-17b-605** is amended to read:

58-17b-605. Therapeutically equivalent and similar drug products.

(1) For the purposes of this section:

(a) "Biological product" means the same as that term is defined in 42 U.S.C. Sec. 262.

(b) (i) "Drug" is as defined in Section 58-17b-102.

(ii) "Drug" [~~does not mean a "biological product" as defined in Section 58-17b-605.5~~] includes a biological product.

[~~(b) "Drug product equivalent" means:~~]

[~~(i) a drug product that is designated as the therapeutic equivalent of another drug product in the Approved Drug Products with Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research of the United States Food and Drug Administration; and~~]

[~~(ii) notwithstanding Subsection (1)(b)(i), an appropriate substitute for albuterol designated by division rule made under Subsection (9).~~]

(c) "Orange book" means the Approved Drug Products with Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research of the United States Food and Drug Administration or its successor publication as determined by the division.

(d) "Osteopathic Physician and Surgeon's Licensing Board" means the board created in Section 58-68-201.

(e) "Physicians Licensing Board" means the board created in Section 58-67-201.

(f) "Purple book" means the database of biological products prepared by the Center for Drug Evaluation and Research of the United States Food and Drug Administration or its successor database as determined by the division.

(g) "Therapeutically equivalent drug product" means a drug product that:

(i) is designated as the therapeutic equivalent of another drug product in the orange book;

(ii) is designated as a biosimilar or interchangeable product in the purple book; or

(iii) (A) has the same amount of the same active ingredient as another drug product; and

(B) is on the list of therapeutically equivalent drug products created by the division in accordance with Subsection (9).

(h) "Therapeutically similar drug product" means a drug product that:

(i) provides the same level of therapeutic benefit and risk to a patient as another drug product; and

(ii) is on the list of therapeutically similar drugs created by the division in accordance with Subsection (9).

(2) A pharmacist or pharmacy intern dispensing a prescription order for a specific drug by brand or proprietary name may substitute [~~a drug product equivalent for the prescribed drug only~~] the prescribed drug with:

(a) a therapeutically equivalent drug product if:

[~~(a)~~] (i) the purchaser specifically requests or consents to the substitution of a [~~drug product equivalent~~] therapeutically equivalent drug product;

[~~(b)~~] (ii) the [~~drug product equivalent~~] therapeutically equivalent drug product is:

(A) of the same generic type and is designated the therapeutic equivalent in the [~~approved drug products with therapeutic equivalence evaluations prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration~~] orange book;

(B) designated as a biosimilar or interchangeable product in the purple book; or

(C) listed on the therapeutically equivalent drug list described in Subsection (9) as a drug that can be substituted for the prescribed drug;

[~~(c)~~] (iii) the [~~drug product equivalent~~] therapeutically equivalent drug product is permitted to move in interstate commerce;

[~~(d)~~] (iv) the pharmacist or pharmacy intern counsels the patient on the use and the expected response to the prescribed drug, whether a substitute or not[~~, and~~];

(v) the substitution is not otherwise prohibited by [~~this chapter;~~] law; and

[~~(c)~~] (vi) the prescribing practitioner has not indicated that a [~~drug product equivalent~~] therapeutically equivalent drug product may not be substituted for the drug, as provided in Subsection (6); [~~and~~] or

[~~(f) the substitution is not otherwise prohibited by law.~~]

(b) a therapeutically similar drug product if:

(i) the prescriber has written "therapeutically similar substitution allowed" on the prescription for the prescribed drug;

(ii) the therapeutically similar drug product is listed on the therapeutically similar drug list described in Subsection (9) as a drug that can be substituted for the prescribed drug;

(iii) the purchaser specifically requests or consents to the substitution of the therapeutically similar drug;

(iv) the dispensed therapeutically similar drug product is permitted to move in interstate commerce;

(v) the pharmacist or pharmacy intern counsels the patient on the use and the expected response to the therapeutically similar drug product;

(vi) the substitution is not otherwise prohibited by law; and

(vii) the substitution:

(A) results in a decreased cost to the patient;

(B) is covered on the patient's health benefit plan formulary as a preferred drug or at the same or lower payment tier;

(C) is necessary because the pharmacist does not have the originally prescribed medication available to dispense to the patient; or

(D) would be beneficial to the patient for any reason if the patient and pharmacist mutually agree that the substitution would benefit the patient.

(3) (a) Each out-of-state mail service pharmacy dispensing a [~~drug product equivalent~~] therapeutically equivalent drug product or a therapeutically similar drug product as a substitute for another drug into this state shall notify the patient of the substitution either by telephone or in writing.

(b) Each out-of-state mail service pharmacy shall comply with the requirements of this chapter with respect to a [~~drug product equivalent~~] therapeutically equivalent drug product or a therapeutically similar drug product substituted for another drug, including labeling and record keeping.

(4) [~~Pharmacists or pharmacy interns may not substitute without the prescriber's authorization on trade name drug product prescriptions unless the product is currently~~

~~categorized in the approved drug products with therapeutic equivalence evaluations prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration as a drug product considered to be therapeutically equivalent to another drug product.~~] A pharmacist or pharmacy intern that substitutes a drug for a therapeutically similar drug under Subsection (2)(b), for any prescription intended to last longer than 30 days, shall notify the prescriber that the pharmacist or pharmacy intern substituted the drug.

(5) A pharmacist or pharmacy intern who dispenses a prescription with a [~~drug product equivalent~~] therapeutically equivalent drug product or a therapeutically similar drug product under this section assumes no greater liability than would be incurred had the pharmacist or pharmacy intern dispensed the prescription with the drug product prescribed.

(6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the patient that a [~~drug product equivalent~~] therapeutically equivalent drug product not be substituted for a prescribed drug, the practitioner may indicate a prohibition on substitution either by writing "dispense as written" or signing in the appropriate space where two lines have been preprinted on a prescription order and captioned "dispense as written" or "substitution permitted".

(b) If the prescription is communicated orally by the prescribing practitioner to the pharmacist or pharmacy intern, the practitioner shall indicate the prohibition on substitution and that indication shall be noted in writing by the pharmacist or pharmacy intern with the name of the practitioner and the words "orally by" and the initials of the pharmacist or pharmacy intern written after it.

(7) (a) A pharmacist or pharmacy intern who substitutes a [~~drug product equivalent~~] therapeutically equivalent drug product or therapeutically similar drug product for a prescribed drug shall communicate the substitution to the purchaser.

(b) The [~~drug product equivalent~~] therapeutically equivalent drug product container or therapeutically similar drug product container shall be labeled with the name of the drug dispensed[~~, and the~~].

(c) The pharmacist, pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both the name of the prescribed drug and the name of the [~~drug product equivalent~~] therapeutically equivalent drug product or the therapeutically similar drug product dispensed in [~~its~~] place of the prescribed drug.

(8) (a) For purposes of this Subsection (8), "substitutes" means to substitute:

(i) a generic drug for another generic drug;

(ii) a generic drug for a nongeneric drug;

(iii) a nongeneric drug for another nongeneric drug; or

(iv) a nongeneric drug for a generic drug.

(b) A prescribing practitioner who makes a finding under Subsection (6)(a) for a patient with a seizure disorder shall indicate a prohibition on substitution of a [~~drug product equivalent~~] therapeutically equivalent drug product in the manner provided in Subsection (6)(a) or (b).

(c) Except as provided in Subsection (8)(d), a pharmacist or pharmacy intern who cannot dispense the prescribed drug as written, and who needs to substitute a [~~drug product equivalent~~] therapeutically equivalent drug product for the drug prescribed to the patient to treat or prevent seizures shall notify the prescribing practitioner prior to the substitution.

(d) Notification under Subsection (8)(c) is not required if the [~~drug product equivalent~~] therapeutically equivalent drug product is paid for in whole or in part by Medicaid.

(9) (a) [~~The division shall designate by rule made in~~] In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, and in consultation with the board, the Physicians Licensing Board [~~created in Section 58-67-201,~~] and the Osteopathic Physician and Surgeon's Licensing Board [~~created in Section 58-68-201, appropriate substitutes for albuterol.~~], the division shall create:

(i) a therapeutically similar drug product list that contains a list of drug products that are therapeutically similar to another drug product.

(ii) a therapeutically equivalent drug product list that contains a list of drug products that are therapeutically equivalent to another drug product

(b) [~~Subsections (2)(b) and (4) do not apply to the substitution of a drug product equivalent for albuterol.~~] The division may not add a drug product to a list described in Subsection if the addition is opposed by:

(i) the board;

(ii) the Physicians Licensing Board; or

(iii) the Osteopathic Physician and Surgeon's Licensing Board.

(c) When creating a list described in Subsection (9)(a), before considering any other

types of drugs, the division shall consider:

(i) albuterol inhalers;

(ii) injectable forms of insulin; and

(iii) diabetic test strips.

(d) The division may:

(i) create standards in rule for considering drug products that should be added to a list described in Subsection (9)(a); or

(ii) examine any peer-reviewed scientific literature when adding a drug to a list described in Subsection (9)(a).

(10) Failure of a licensed medical practitioner to specify that no substitution is authorized does not constitute evidence of negligence.

Section 2. **Repealer.**

This bill repeals:

Section **58-17b-605.5, Interchangeable biological products.**

Section 3. **Effective date.**

This bill takes effect on May 1, 2024.